approaches—based mainly on fostering individual technical expertise—have not always guaranteed good quality care. In this sense there can be said to be a health care crisis, even at a time when people are living longer than ever before.

The integration of quality management concepts into the core activities of the clinical professions would enable their members to participate more fully in economic and financially based management decisions about health service development. Contrary to the fears of some of those concerned to eliminate neglect and inadequate care, this would not mean that clinicians would have to accept suboptimal standards of individual patient care as desirable on overall "quality" grounds. Rather, it should equip members of the clinical professions to work more effectively with each other and their non-clinical colleagues in the interests of their patients, and as members of their organisations. This in turn would help professionals to recover some key aspects of their eroded authority, and to ensure publicly acceptable balance in the processes of institutional and system wide health care decision making.

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Over the Counter Drugs

Patients, society, and the increase in self medication

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OTC

This is the first of four articles examining the implications of the availability and use of non-prescription medicines for health services in Britain and elsewhere

Self medication with over the counter medicines has long been a feature of the lay health system. With the reclassification of certain drugs, the public can buy preparations that were previously available only on prescription. Sales of over the counter medicines are now equivalent to a third of the NHS drugs bill; governments throughout the world see self medication as a way of shifting some of the cost of health care onto consumers. The trend towards increased self care and with it the increasing empowerment of patients has many potential benefits; collaboration between doctors and pharmacists will be critical.

Over any two week period, nine out of 10 adults will report having experienced at least one ailment.[1,2] Non-prescription medicines, commonly known as over the counter or OTC medicines, are used to treat one in four of these episodes.[2] Sales of over the counter medicines in pharmacy and grocery outlets reached £1268·5 million in 1994 (box 1)—about a third of the NHS drugs bill of £3·6 billion.

Box 1—Market breakdown for major categories of non-prescription medicines[3]

Pain	£196·4m (16·7%)
Skin	£143·5m (11·3%)
Cold	£93·9m (7·4%)
Cough	£68·1m (5·4%)
Sore throat	£72·7m (5·7%)
Indigestion	£73·9m (5·8%)
Total market (1994)	£1268·5m

In the late 1980s the government fuelled the over the counter market by making it easier to reclassify certain medicines from prescription only status to allow over the counter sale in pharmacies. Progress was slow at first, with 11 medicines being reclassified between 1983 and 1992 (table 1), but since 1992 a further 40 medicines have been reclassified. This widened range of non-prescription medicines has highlighted the role of pharmacists, to whom the public is increasingly looking for advice.

Box 2—Factors promoting and inhibiting the reclassification of drugs to pharmacy status

Promoters:
- Patient empowerment (increase in the autonomy ethic)
- Rise of consumerism
- Decreasing power of the professions
- Changing balance of power within the professions
- Pharmacists' drive to extend their role
- Government policy to contain the NHS drugs bill
- Possible influence of health care systems outside Britain
- Pharmaceutical companies' wish to protect profits

Inhibitors:
- Professionals' protection of their domain
- Doubts about patients' competence in self care
- Pharmacists' anxieties about increased responsibility

What is driving the POM to P changes?

Factors promoting and inhibiting the reclassification of drugs are shown in box 2. The deregulation is occurring against a background of pressure on the primary care drugs bill. Self care and self medication with non-prescription medicines are seen by governments throughout the world as a means of shifting some of the responsibility and cost of health care from government and third party payers onto consumers. Increasing scrutiny of NHS prescribing costs has pressured pharmaceutical companies to protect their markets. Reclassification of a drug not only creates potential new business in the non-prescription marketplace but can also promote an existing branded medicine that is also available on prescription. The pharmaceutical industry has therefore—unsurprisingly—embraced the opportunities offered by self medication. So too has the Royal Pharmaceutical Society, which has actively and consistently lobbied for moves from prescription only medicine to pharmacy status.

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Table 1—*Medicines deregulated from prescription only to pharmacy status, 1980-95*

Drug	Non-prescription products	Year of switch*
Acyclovir	Zovirax Cold Sore Cream	1993
Aluminium chloride hexahydrate	Anhydrol Forte, Driclor	1994
Antihistamines:		
Acrivastine		1993
Astemizole	Hismanal, Pollon-eze	1988
Cetirizine	Zirtek	1993
Hydroxyzine		1995
Loratidine	Clarityn	1992
Terfenadine	Triludan	1983
Beclomethasone dipropionate	Beconase Hayfever	1994
Cadexomer iodine	Iodosorb powder	1995
Carbenoxolone granules		1992
Detromethorphan (controlled release)	Coughcaps	1989
Dextranomer topical	Debrisan	1987
Dihydrocodeine/paracetamol (restricted dose)	Paramol	1992
Fluconazole (oral)	Diflucan One	1995
Flunisolide nasal spray	Syntaris Hayfever	1994
H_2 Antagonists		
Cimetidine	Tagamet 100, Tagamet Dual Action	1994
Famotidine	Pepcid AC	1994
Ranitidine	Zantac 75	1994
Hydrocortisone 1% topical	Hc45, Dermacort, Lanacort	1987
Hydrocortisone cream/ointment for mild-moderate eczema	Hc45, Dermacort, Lanacort	1994
Hydrocortisone (haemorrhoidal preparations)	Anusol Plus HC, Proctocream HC	1994
Hydrocortisone 2·5% pellets for aphthous ulcers	Corlan	1994
Hydrocortisone/crotamiton	Eurax HC	1992
Hyoscine butylbromide	Buscopan	1992
Ibuprofen	Various (Nurofen, Proflex, etc)	1983
Ibuprofen (sustained release)	Proflex SR Capsules	1988
Isosorbide dinitrate	Cedocard 20	1988
Ketoconazole 2% shampoo	Nizorval	1995
Loperamide	Arret, Imodium, Diocalm Ultra	1983
Mebendazole	Ovex	1989
Minoxidil 2% topical solution	Regaine	1994
Nicotine gum 2 mg	Nicorette	1991
Nicotine gum 4 mg	Nicorette Plus	1994
Nicotine patches	Niconil, Nicotinell, Nicorette	1992
Non-steroidal anti-inflammatory agents (topical)		
Diclofenac		1994
Felbinac		1994
Ibuprofen	Ibugel, Ibuleve	1988
Ketoprofen	Oruvail Gel	1993
Piroxicam	Feldene P Gel	1994
Oxethazine and aluminium/magnesium hydroxide		1994
Pseudoephedrine (sustained release)		1994
Pyrantel embonate		1995
Sodium cromoglycate eye drops 2%	Various: Opticrom Allergy, Broleze, etc	1994
Terfenadine	Triludan	1984
Tioconazole (external)	Trosyl Dermal Cream	1994
Triamcinolone 0.1% oral paste	Adcortyl in Orabase 5	1994
Vaginal imidazoles:		
Clotrimazole	Canesten	1992
Econazole	Gyno-Pevaryl	1992
Isoconazole		1992
Miconazole	Femeron	1992
Tioconazole		1994

Source: Royal Pharmaceutical Society of Great Britain.
*Denotes year when the legal change was made by statutory instrument; product launches were not necessarily in the same year.

Are over the counter medicines effective?

Although all non-prescription medicines are required to hold a product licence, few have been evaluated in formal clinical trials in the setting in which they will be used. As a result many non-prescription products sold by pharmacists have been criticised for their lack of effectiveness. Yet consumers continue to demand them and claim their worth. A review of studies of over the counter preparations used to treat coughs and colds, for example, concluded that some single ingredient products and some combination products relieved symptoms in older children and adults.[4] The therapeutic effects are better established for medicines that formerly had prescription only status.

How medicines are reclassified

There are three legal categories of medicines—prescription only medicine (POM), pharmacy medicine (P), and general sales list medicine (GSL); the last can be sold from outlets including supermarkets and drugstores. The principle of a class of medicines whose sale requires the supervision of a pharmacist is not unique to the United Kingdom.

The data required for a medicine to be switched from prescription only status are summarised in box 3. According to the Proprietary Association of Great Britain (the association of manufacturers of over the counter medicines), the assessments involved in approving a switch "amount to a relicensing procedure and in addition require the approval of the Committee on Safety of Medicines."[5] Safety and efficacy data must be submitted, and particular attention is paid to information for consumers. New clinical trial data may be needed to support a proposal for deregulation since dosage may be different (lower, generally) than for the prescription only product.[5,6] Safety issues are key in the deregulation process, and there have been calls to extend the adverse drug reaction reporting system,

Box 3—Data required for switching from prescription only to pharmacy status[5]

Safety:

- Epidemiological evidence showing safety in use of the medicine over time
- Adverse drug reaction profile of the dose and form that would be used in the non-prescription product. Such reactions should be minor in nature and severity and should normally cease when treatment is stopped
- Analysis and information on possible risk of incorrect or delayed diagnosis arising from non-prescription use

Efficacy:

- Evidence to support suitability of both indications and dosage for self medication
- Appropriateness of the proposed indications for self medication: well defined and with no overlap with serious conditions. Should be recognisable by consumers and not likely to be confused with potentially serious diseases

Information:

- Product information must meet criteria of leading to safe use and must include warnings and advice on duration of treatment and when medical attention should be sought

using pharmacists to capture data on over the counter medicines.[6]

Is there a conflict of commercial and professional interests for pharmacists?

The Nuffield inquiry into pharmacy[7] recognised the potential for conflict between the pharmacist's code of ethics[8] and the commercial environment of the pharmacy, but it found no evidence that this was a problem in practice. Some general practitioners believe that the business environment of the pharmacy precludes the pharmacist being a member of the primary health care team; others see this as a theoretical rather than real issue.[9] The rise of fundholding has brought with it the more explicit acknowledgement of group medical practices themselves as small or medium sized businesses.

If the profit motive predominated, pharmacists would be expected always to sell a medicine in response to a request for advice. Research shows, however, that in about a quarter of cases no sale is made, and customers are often recommended to see their general practitioner instead.[10] Pharmacists receive no payment for the advice they provide; the service of response to symptoms has, until now, been regarded as outside of the NHS. Discussions on the professional allowance which forms part of the community pharmacy NHS contract might usefully consider the incorporation of an element for such advice, perhaps linked to quality indicators including completion of relevant training and participation in audit.

There has been little research to follow up customers who are referred to their general practitioner by the pharmacist, although one small study found that over three quarters of those advised to see their doctor did so.[11] The question remains as to the appropriateness of pharmacist referrals, and this is an area where pharmacists and general practitioners need to collaborate in clinical audit.

Another area where audit is needed is the basis on which pharmacists select medicines for recommendation. There have been calls for the establishment of formularies for over the counter medicines and a greater emphasis on the scientific basis of product selection.[12,13] Research in Australia has examined the influences on pharmacist prescribing, including scientific evidence and commercial pressures,[14] but similar research is needed in Britain. Given the efforts made by manufacturers to persuade pharmacists to stock and recommend particular products, it is important for pharmacists to show that independent and impartial judgments are being made.

The international perspective

The trend to make more medicines available for self medication is evident across Europe, although differences in, for example, reimbursement policies have caused problems in some countries. The Danish government announced in 1989 that it proposed to deregulate 81 products with the aim of saving £90m a year on the drugs bill by withdrawing prescription reimbursement.[15] This effectively denied the drugs to those who could not afford the full cost; the policy of total non-reimbursement was subsequently adjusted. A recent review of use of cimetidine, which has been sold over the counter in Denmark since 1989, concluded that there was no evidence that serious conditions were being masked or that adverse drug reactions had increased.[16]

In North America the Food and Drugs Administration began reviewing its over the counter drugs programme in 1972, with the aim of increasing the number of products available to consumers. Forty five compounds were deregulated between 1972 and 1994. There is no "pharmacy only" sale category in the United States, so deregulated medicines can be sold anywhere, including supermarkets and local stores.

Medicines reclassification in Australia and New Zealand has run along similar lines to those in Britain. New Zealand has a legal requirement for pharmacists to provide counselling and keep records for certain "restricted medicines." Another important difference is that β_2 agonist inhalers have been available over the counter in Australia since 1985, with a stipulation that sales can be made only through pharmacies and that the pharmacist must deal personally with the transaction. Over the counter purchase of inhalers has been found to be associated with infrequent consultation with the doctor and undertreatment of asthma.[17] Use of over the counter medication, the researchers

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Keeping up with the demand for over the counter medicines

hypothesise, may be a marker for "difficult" patients who want to avoid contact with medical services—an interesting possible outcome of increased consumer choice.

Sources of information about over the counter medicines

Advertising of over the counter medicines appears in a variety of media, including television, newspapers, magazines, leaflets, and direct mail. Before publication, all advertising is vetted by the Proprietary Association of Great Britain, which operates a code of standards of advertising practice for over the counter medicines. The self regulatory system seems to work well—in contrast, for example, to the situation in Denmark, where the government's response to complaints about advertising led to direct intervention and advertising restrictions.[15]

Pharmacists in the United Kingdom have expressed their concerns about television advertising of medicines and, more recently, direct mailings to members of the public. Closer working between pharmaceutical companies and health professionals is needed if these issues are to be resolved. Experience in Sweden indicates that the importance of advertisements as an information source decreases with time from product launch and that the influence of pharmacists increases.[18]

Leaflets included with over the counter medicines are another important information source, although the readability of some is poor.[19] Innovative approaches are needed to make them more understandable by the general population, and ethnic groups need materials in different languages. Pharmacists frequently give verbal advice and information about over the counter medicines, but patients' recall of this advice is low.[20] Good written information is an important way to reinforce verbal advice.

Doctors receive little or no formal teaching about over the counter medicines at undergraduate or postgraduate level. The *British National Formulary* carries information on medicines that have been reclassified, including doses, indications, and proprietary brands, and the "Current Problems" bulletin of the Committee on Safety of Medicines also carries a regular item on recently deregulated medicines. Since 1993 the Proprietary Association of Great Britain has supplied every general practitioner in the United Kingdom with a copy of the *OTC Directory*, an illustrated guide to available proprietary products.[21] General practitioners are therefore in a strong position to recommend, where appropriate, that a patient purchase an over the counter medicine. Guidance from the Department of Health states that so long as the patient is offered the option of an NHS prescription, doctors can suggest an over the counter purchase. As the inexorable rise of the prescription item charge continues, many over the counter medicines now cost less, and concern has been expressed about how the increase in self medication is contributing towards the "creeping privatisation of the NHS."[22]

The future

The trend towards increased self care and, with it, self medication with ever more powerful drugs seems unstoppable. The potential benefits of this trend, with the increasing empowerment of patients, are many. Nevertheless, developments in self medication will need to be carefully managed if these benefits are to be maximised and the potential risks kept to a miminum. Greater collaboration between doctors and pharmacists will be critical and joint training on over the counter medicines helpful.[23] In addition, professional bodies and consumer and patient groups need to look closely at how they can build stronger alliances.

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ANY QUESTIONS

Is there any evidence to support the view that early retirement is associated with increased life span?

No. Several studies that examined this question have indicated that early retirement is related to higher mortality, even when health conditions that may have contributed to early retirement are accounted for.[1,2] Other studies have not found an excess mortality among people who retire early,[3] but no well controlled investigation has shown any survival advantage of early retirement. It is possible that the association between mortality and early retirement reflects subtle unreported health problems that have contributed to the decision to retire or that the association, if real, is restricted to forced retirement or involuntary loss of employment. If this were the case it is conceivable that voluntary early retirement of apparently healthy people could have beneficial effects for some of them, but empirical evidence in support of this hypothesis is lacking.—DIMITRIOS TRICHOPOULOS *is professor and chairman, department of epidemiology, Harvard School of Public Health, Boston, USA*

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